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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/687,892	10/17/2003	Jose A. O'Daly	17595-3	1782

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PATENT DOCKET ADMINISTRATOR
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EXAMINER	
GRASER, JENNIFER E	

ART UNIT	PAPER NUMBER
1645	

MAIL DATE	DELIVERY MODE
12/28/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/687,892	O'DALY, JOSE A.	
	Examiner	Art Unit	
	Jennifer E. Graser	1645	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *27 September 2007*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *55-89* is/are pending in the application.

4a) Of the above claim(s) *72-89* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *55-71* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office Action.

Acknowledgment and entry of the Amendment submitted on 9/27/07 is made. Claims 55-89 are currently pending. Claims 72-89 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention.

Claims 55-71 are currently under examination.

Former Rejections Withdrawn

1. The former rejection of the claims on the grounds of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-18 of U.S. Patent No. 6,673,351 has been overcome by the Terminal Disclaimer which was filed on 9/27/07.

Applicants' amendments to the claims has obviated the former 112, 2nd paragraph rejection and the former 112, first written description rejection.

Claim Rejections - 35 USC § 112-Enablement

2. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

3. Claims 55-71 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

Enablement requires that the specification teach those in the art to make and use the invention without undue experimentation. Factors to be considered in determining whether a disclosure would require undue experimentation include (1) the nature of the invention, (2) the state of the prior art, (3) the predictability or lack thereof in the art, (4) the amount of direction or guidance present, (5) the presence or absence of working examples, (6) the quantity of experimentation necessary, (7) the relative skill of those in the art, and (8) the breadth of the claims.

The instant claims are broadly drawn to a composition for treatment of psoriasis comprising *any* polypeptide comprising at least one of the amino acid sequences set forth in SEQ ID Nos: 1-14. The polypeptides set forth in SEQ ID Nos: 1-14 are as small as 6 amino acids to 16 amino acids in length, averaging around 8 amino acids in length. Additionally, the fragments appear to be from several different proteins. The instant specification has not shown that any one of these *single* polypeptides (as encompassed by the claims), e.g., SEQ ID NO: 1-14, may treat psoriasis. There are no results using these single epitopes. It is not clear how much of these single polypeptides (from 6-16 amino acids in length) or in what mixture (e.g., any one of..) would be needed to constitute 'an effective amount to treat psoriasis". The specification has enabled the use of the full-length polypeptides in extracts which are 73 (comprises SEQ ID Nos: 11, 12, 13 and 14), 80 (comprises SEQ ID Nos: 1, 3 and 10) and 82 kDA (comprises SEQ ID Nos: 7, 8 and 9) for the abatement of clinical symptoms of psoriasis (patented in US 6,673,351). However, the specification has not shown that any single polypeptide represented by a sequence in SEQ ID NOS: 1-14 or a mixture of one, or 2, etc. may

treat psoriasis. Additionally, the specification has only demonstrated that the full-length polypeptide extracts may be used to abate the clinical symptoms of psoriasis, but not fully treat the disease. The instant specification teaches three "generations' of immunotherapeutic agents all which comprise different polypeptide profiles. Example 2 on page 16 of the instant specification teaches that the immunogen preparations of the second-generation immunotherapeutic agent, contain protein fractions 3 and 4 obtained afer DEAE-chromatography and total reduction and alkylation, and had three bands with molecular weights of 73, 80 and 82 kDa, e.g, the compostion which is instantly claimed. It is taught on page 36 that immunotherapeutic agents comprising protein fractions 3 and 4, resulted in significant stimulation of lymphocytes which resulted in inhibition of the inflammatory response in psoriatic patients, thus inducing clinical remission of the psoriatic lesions. Example 16 provides further results of the fraction comprising the 73, 80 and 82kDa antigens obtained by the method as set forth in the 'enabled' portion of the scope of enablement rejection above. The specification fails to teach any other fractions, extracts or particulate antigens which would work in a similar manner as proteins fractions 3 and 4. Since the components of fractions 3 and 4 are not clearly set forth, the method used to obtain them is necessary in order to establish the bounds of patent protection. It does not appear that any extract or particulate antigen comprising polypeptides with molecular weights similar or identical to those recited in instant claim 55, rather it was the method of obtaining the fractions which resulted in an extract with the specific immunotherapeutic properties. The claims should be limited accordingly. Genentech Inc. v. Novo Nordisk A/S (CAFC) 42 USPQ2d 1001 clearly states: "Patent

protection is granted in return for an enabling disclosure of an invention, not for vague intimations of general ideas that may or may not be workable. See Brenner v. Manson, 383 U.S. 519, 536, 148 USPQ 689, 696 (1966) (stating, in context of the utility requirement, that "a patent is not a hunting license. It is not a reward for the search, but compensation for its successful conclusion.") Tossing out the mere germ of an idea does not constitute enabling disclosure. While every aspect of a generic claim certainly need not have been carried out by an inventor, or exemplified in the specification, reasonable detail must be provided in order to enable members of the public to understand and carry out the invention."

Given the lack of guidance contained in the specification, one of skill in the art could not make or use the broadly claimed invention without undue experimentation.

Claim Rejections - 35 USC § 102

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
>
> (e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

5. Claims 55-71 are rejected under 35 U.S.C. 102(b) as being anticipated by O'Daly et al (Gac Med Caracas, 103(2): 133-177, 1995).

O'Daly et al teach a preparation of a vaccine from Leishmania parasite strains, *L.amazonenis, L.venezuelensis, L.brasiliensis, and L.chagasi.* Each parasite was

cultivated and was incubated at the particular temperature of transformation into the amastigote form. Once the parasite reached the amastigote stage they were subjected to a medium with an agent effective to kill the parasites. The parasites were harvested by centrifugation and washed. The isolated parasites were treated by incubation with a medium comprising a detergent, which extracts some proteins from the parasite. The proteins in the total extract were further fractionated and purified by centrifugation. Washing repeatedly further refined the centrifugation pellet comprising fractionated particulate isolated proteins; and, the supernatant fraction containing other *Leishmania* proteins was not further used. This centrifugation step is seen as fractionating and purifying the particulate proteins from the detergent extracted proteins and is fact purifying the particulate protein fraction from that solubilized by the detergent medium. The purified/fractionated particulate proteins from the detergent extract were resuspended in medium and then sonicated. The protein content of the extracted sonicate was determined and alumina was added at a concentration of 1mL/mg of protein of each one of the *Leishmania* parasite strains, which were added in equal parts to obtain a final concentration of 1000ug/ml of *Leishmania* antigen. See page 1 of the translation of the article, under "Preparation of vaccine". The process of preparing the *Leishmania* vaccine extract according to O'Daly is substantially the same as that provided for in the specification at pages 3-4 and pages 11-12. Therefore, the composition of a purified protein extract comprising isolated polypeptides that is used in the claimed method appears to be the same as the compositions of the prior art. *The identification of an amino acid sequence of an already known polypeptide does not*

impart novelty. The proteins contained therein are in fact extracted/isolated/purified from the total amastigote form of the parasite to the same extent as provided for in the extracts of the specification. The recitation of the partial sequences from the *Leishmania* polypeptides found in the composition of the prior art is merely further characterization of the polypeptides of the prior art composition.

Although O'Daly does not specifically recite the amino acid sequences of their claimed polypeptides, the sequences are an inherent property of the composition of the prior art, especially given the identity of the source and the method in which the extracts were obtained. The disclosed extracts of the prior art reference appear to be identical to Applicants' claimed compositions. Since the Patent Office does not have the facilities for examining and comparing Applicant's extract/particulate antigen with the extract of the prior art, the burden of proof is upon applicants to show an unobvious distinction between the material structural and functional characteristics of the claimed antigen and the extract of the prior art. See In re Best, 195 USPQ 430, 433 (CCPA 19&&). The phrase "to treat psoriasis" is an intended use only. A recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim. A "pharmaceutically acceptable carrier" reads on water and would be inherent in the prior art compositions.

Response to Applicant's Arguments:

Applicants argue that O'Daly does not reach what is a 'therapeutically effective amount to treat psoriasis', let alone a composition comprising any one of SEQ ID Nos:

1-14. These arguments have been fully and carefully considered but are not deemed persuasive. It is noted that the instant specification does not teach what is is a 'therapeutically effective amount to treat psoriasis' of any one of SEQ ID Nos: 1-14 to treat psoriasis. See enablement rejection above. Regarding the sequence identifiers, *The identification of an amino acid sequence of an already known polypeptide does not impart novelty*. The proteins contained therein are in fact extracted/isolated/purified from the total amastigote form of the parasite to the same extent as provided for in the extracts of the specification. The recitation of the partial sequences from the *Leishmania* polypeptides found in the composition of the prior art is merely further characterization of the polypeptides of the prior art composition.

Although O'Daly does not specifically recite the amino acid sequences of their claimed polypeptides, the sequences are an inherent property of the composition of the prior art, especially given the identity of the source and the method in which the extracts were obtained. The disclosed extracts of the prior art reference appear to be identical to Applicants' claimed compositions. Since the Patent Office does not have the facilities for examining and comparing Applicant's extract/particulate antigen with the extract of the prior art, the burden of proof is upon applicants to show an unobvious distinction between the material structural and functional characteristics of the claimed antigen and the extract of the prior art. See In re Best, 195 USPQ 430, 433 (CCPA 19&&). The phrase "to treat psoriasis" is an intended use only. A recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from

the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim. A "pharmaceutically acceptable carrier" reads on water and would be inherent in the prior art compositions.

6. Claims 55-71 are rejected under 35 U.S.C. 102(e) as being anticipated by Lesmare (US Patent No. 6,458,581 B1).

Lesmare teaches polypeptide extracts of short-term promastigote forms and total polypeptide extracts of amastigote forms at different stages of their growth in vitro. See column 7. The reference teaches that the extracts can be obtained from any species of Leishmania, and expressly mentions L.braziliensis, L.amazonensis, and L.chagasi. See column 6, lines 45-50. Gel electorphoresis revealed numerous polypeptides with molecular weights ranging from about 60-85 kDa. Column 34, line 44, teaches a 70Kda polypeptide from L.infantum, column 27 teaches an L.amazonensis polypeptide extract comprising an ~80kDa polypeptide, column 25 teches an ~ 85 kDa protein from L.donovani, 90kDa polypeptides are taught. The reference teaches these polypeptides are comprised in a total polypeptide extract. The instant claims use the open language 'comprising' and allow for the inclusion of additional polypeptides. Addtionally, although Lesmare does not specifically recite the amino acid sequences of their claimed polypeptides, they would inherently be that of any one of SEQ ID Nos: 1-14, given the identity of the source and the method in which the extracts were obtained, the disclosed extracts of the prior art reference appear to be identical to Applicants' claimed extract. Since the Patent Office does not have the facilities for examining and comparing Applicant's extract/particulate antigen with the extract of the prior art, the burden of

proof is upon applicants to show an unobvious distinction between the material structural and functional characteristics of the claimed antigen and the extract of the prior art. See In re Best, 195 USPQ 430, 433 (CCPA 19&&). The phrase "to treat psoriasis" is an intended use only. A recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim.

Response to Applicant's Arguments:
Applicants argue that O'Daly does not reach what is a 'therapeutically effective amount to treat psoriasis', let alone a composition comprising any one of SEQ ID Nos: 1-14. These arguments have been fully and carefully considered but are not deemed persuasive. It is noted that the instant specification does not teach what is is a 'therapeutically effective amount to treat psoriasis' of any one of SEQ ID Nos: 1-14 to treat psoriasis. See enablement rejection above. Regarding the sequence identifiers, *The identification of an amino acid sequence of an already known polypeptide does not impart novelty*. The reference teaches that the extracts can be obtained from any species of Leishmania, and expressly mentions L.braziliensis, L.amazonensis, and L.chagasi. See column 6, lines 45-50. Gel electorphoresis revealed numerous polypeptides with molecular weights ranging from about 60-85 kDa. Column 34, line 44, teaches a 70Kda polypeptide from L.infantum, column 27 teaches an L.amazonensis polypeptide extract comprising an ~80kDa polypeptide, column 25 teches an ~ 85 kDa protein from L.donovani, 90kDa polypeptides are taught. The reference teaches these polypeptides are comprised in a total polypeptide extract. The instant claims use the

open language 'comprising' and allow for the inclusion of additional polypeptides. Addtionally, although Lesmare does not specifically recite the amino acid sequences of their claimed polypeptides, they would inherently be that of any one of SEQ ID Nos: 1-14, given the identity of the source and the method in which the extracts were obtained, the disclosed extracts of the prior art reference appear to be identical to Applicants' claimed extract. Since the Patent Office does not have the facilities for examining and comparing Applicant's extract/particulate antigen with the extract of the prior art, the burden of proof is upon applicants to show an unobvious distinction between the material structural and functional characteristics of the claimed antigen and the extract of the prior art. See In re Best, 195 USPQ 430, 433 (CCPA 19&&). The phrase "to treat psoriasis" is an intended use only. A recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim.
7.Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any

extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

8. Correspondence regarding this application should be directed to Group Art Unit 1645. Papers related to this application may be submitted to Group 1600 by facsimile transmission. Papers should be faxed to Group 1600 via the PTO Fax Center located in Remsen. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15,1989). The Group 1645 Fax number is 571-273-8300 which is able to receive transmissions 24 hours/day, 7 days/week.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jennifer E. Graser whose telephone number is (571) 272-0858. The examiner can normally be reached on Monday-Thursday from 7:30 AM-6:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's acting supervisor, Shanon Foley, can be reached on (571) 272-0898.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (571) 272-0500.

Jennifer Graser
Primary Examiner
Art Unit 1645

12/11/07